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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,664	01/22/2004	David J. Beebe	282.033	5152

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EXAMINER	
GILBERT, ANDREW M	

ART UNIT	PAPER NUMBER
3767	

NOTIFICATION DATE	DELIVERY MODE
04/03/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/762,664	BEEBE ET AL.	
	Examiner	Art Unit	
	ANDREW M. GILBERT	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9,17,20,21 and 24-27* is/are pending in the application.

4a) Of the above claim(s) *9,17,20 and 25* is/are withdrawn from consideration.

5)☒ Claim(s) *24 and 26* is/are allowed.

6)☒ Claim(s) *21 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/19/2008 has been entered.

Acknowledgments

1. This office action is in response to the reply filed on 2/19/2009 and 1/26/2009.

2. In the reply, the Applicant amended claims 21 and 27 and cancelled claim 28. Claims 24 and 26 were previously indicated as allowable. Claims 9, 17, 20, 25 are withdrawn.

3. Thus, claims 21, 24, 26, and 27 remain pending.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 27 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had

possession of the claimed invention. Claim 27 recites "an aqueous solution having a predetermined physical property". However, the applicant does not disclosure in his original disclosure *any predetermined physical property* of an aqueous solution and instead discloses a predetermined condition, but not a predetermined physical property of an aqueous solution. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 21 is rejected under 35 U.S.C. 102(e) as being anticipated by Ziaie et al (2004/0248326). Ziaie et al discloses in reference to claim 21 a microfluidic device (Fig 13) for delivering a drug to an individual, comprising: a body (504) defining a reservoir for receiving the drug and a chamber for receiving an aqueous solution therein ([0028] wherein the insulin pump may be an osmotic pump which are well known in the art to have a drug contained in a reservoir formed by a membrane surrounding the drug, a osmotic agent containing chamber between the membrane a semipermeable membrane holding the osmotic agent and the semipermeable membrane being capable of being permeable to an aqueous solution which flows through the semipermeable membrane increasing the volume of the chamber and exerting pressure on the reservoir); an output cannula (502) having an input in communication with the reservoir (Fig 13) and an output receivable within the individual (Fig 13); an aqueous solution

injectable into the chamber of the body (see external solution diffusion for example Fig 12; the examiner notes that the scope of injectable into the chamber is very broad and the applicant has not structurally defined the method of injection; thus, where an aqueous solution traverses a field into the chamber the aqueous solution is said to have been injectable into the chamber; and response to arguments below); an adhesive (Fig 13) for affixing the body to the individual; a pressure source (see discussion above) including an hydrogel member received within the chamber (wherein the osmotic agent may be considered a hydrogel [0145]) and being expandable in response to exposure to a the aqueous solution (see discussion above), the hydrogel member engageable with the reservoir and urging the drug from the reservoir through the output cannula as the hydrogel member expands ([0143-0147]); and a valve (500; Fig 9-10) defining a chamber and interconnecting the reservoir and the output cannula (Fig 13), the valve movable between a non-actuated position wherein the valve prevents the flow of the drug from the reservoir to the output needle and an actuated position wherein the valve allows for the flow of the drug from the reservoir to the output needle (Fig 9-10, 13; [0017, 0028, 0143-0147] and discussion of "Hydrogel-Activated Devices").

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claim 21, 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kriesel et al (6416495) in view of Kriesel et al (5693018). In reference to claim 21 Kriesel et al '495 discloses a microfluidic device (Fig 4) for delivering a drug to an individual, comprising: a body (24) defining a reservoir (44) for receiving the drug and defined by a membrane (50) and a chamber (70) for receiving an aqueous solution therein; an output cannula (137) having an input in communication with the reservoir (Fig 4) and an output receivable within the individual (Fig 3, 4, Summary); an aqueous solution injectable into the chamber of the body (see col 7, lns 1-21 for example; the examiner notes that its clear the hydrogel is disclosed as being activated by a variety of methods including solvent concentration – the only way that could occur is if solvent could be delivered into the chamber; and response to arguments below) a pressure source (70) including an hydrogel member received within the chamber (70) and being expandable in response to exposure to the aqueous solution (col 6, lns 33-47, col 10, lns 9-21; and specifically col 7, lns 1-32 or col 9 lns 56-58; wherein the hydrogel is disclosed as being the type that responds to a ph or salt concentration change that occurs in an aqueous solution), the hydrogel member engageable with the reservoir and urging the drug from the reservoir through the output cannula as the hydrogel member expands (Fig 4, Summary, col 5, lns 15-col 6, lns 1, col 6, lns 33-47, col 10, lns 9-21); and a valve (64) defining a chamber and interconnecting the reservoir and the output cannula (Fig 4), the valve movable between a non-actuated position wherein the valve prevents the flow of the drug from the reservoir to the output needle and an actuated

position wherein the valve allows for the flow of the drug from the reservoir to the output needle (64, Fig 4, Summary, col 5, lns 15-col 6, lns 1, col 6, lns 33-47, col 10, lns 9-21).

8. In response to claims 27, Kriesel et al '495 discloses the invention substantially as claimed and further discloses that the hydrogel member is expandable in response to exposure to a predetermine physical property originating within the body (col 6, lns 33-47, col 10, lns 9-21; and specifically col 7, lns 1-32 or col 9 lns 56-58; wherein the hydrogel is disclosed as being the type that responds to a ph or salt concentration change that occurs in an aqueous solution; furthermore, see col 11, col 21-25, wherein a sensor is exposed to a predetermined physical property originating within the body in the bloodstream which is an aqueous solution. In this case, the sensor can activating any one of the disclosed (magnetic, light, electrical) methods of activating the hydrogel member in response to an exposure to a predetermine physical property originating within the body.

9. However, Kriesel et al '495 does not expressly disclose that the output cannula is a needle and that the device has an adhesive for affixing the body to the individual.

10. Kriesel et al '018 teaches that it is known to have the output cannula is a needle (26b) and that the device has an adhesive (layer "A") for affixing the body to the individual for the purpose of providing a subdermal insulin delivery device that is attached to the patient's skin. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the output cannula and device as taught by Kriesel et al '495 with the output needle and adhesive securement as taught

by Kriesel et al '018 for the purpose of a subdermal insulin delivery device that is attached to the patient's skin.

11. Claims 21, 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eckenhoff et al (4552561) in view of Ziaie et al (20040248326). Eckenhoff et al discloses a microfluidic device (Fig 2) for delivering a drug to an individual, comprising: a body (2) defining a reservoir (25) for receiving the drug and being defined by a membrane (16) and a chamber (11) for receiving an aqueous solution (18) therein; an output cannula (22, 21) having an input in communication with the reservoir (Fig 2) and an output receivable within the individual (Fig 2); an aqueous solution injectable into the chamber of the body (see col 6, lns 20-28 wherein the hydogel and the aqueous activating solution are both filled into the chamber via a tube; this fully reads on "injectabled into the chamber"; and response to arguments below) a pressure source (18) including an hydrogel member received within the chamber and being expandable in response to exposure to a the aqueous solution (see discussion above), the hydrogel member engageable with the reservoir and urging the drug from the reservoir through the output cannula as the hydrogel member expands ([col 4, lns 15-35; col 5, lns 53-43]); an output needle (22), and an adhesive (6). *The Examiner also references col 6, lns 20-28 where it is discussed filling the chamber with the hydrogel via a tube (reads on applicant's claim amendments that are subject to the new matter objection above).*

12. However, Eckenhoff et al does not a valve between the reservoir and the output needle. Ziaie et al teaches that it is known to have a valve (500; Fig 9-10) defining a

chamber and interconnecting the reservoir and the output cannula (Fig 13), the valve movable between a non-actuated position wherein the valve prevents the flow of the drug from the reservoir to the output needle and an actuated position wherein the valve allows for the flow of the drug from the reservoir to the output needle (Fig 9-10, 13; [0017, 0028, 0143-0147] and discussion of "Hydrogel-Activated Devices"); the valve including a hydrogel microscale valve having a flexible membrane (104) for dividing the valve chamber into a drug flow portion (110) and a trigger receiving portion (103) and a trigger (102) position within the trigger receiving portion of the valve chamber and having a first configuration with the valve in the non-actuated position and a second configuration with the valve in the actuated position (Fig 9) for the purpose of controlling drug delivery either in response to a pre-determined stimulus or for pulsatile delivery. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the reservoir to output needle connection as taught by Eckenhoff et al with the hydrogel activated microvalve as taught by Ziaie et al for the purpose of controlling drug delivery either in response to a pre-determined stimulus or for pulsatile delivery.

Allowable Subject Matter

13. Claim 24, 26 is allowed.

Response to Arguments

14. Applicant's arguments with respect to claims 21, 27 have been considered but are not persuasive.

15. The applicant argues that the prior art references do not teach an aqueous solution injected into the chamber. The Examiner disagrees. The scope of the claim limitation "injected into the chamber" is broader – namely, anything introduced into the chamber is injected into the chamber. The prior art references as discussed above in the citations, each meet this claim limitation. The Examiner suggests further structural characterization of this feature to distinguish over the prior art on the record.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW M. GILBERT whose telephone number is (571)272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew M Gilbert/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767